

NMCP COVID-19 Literature Report #81-S: Friday, 19 November 2021

Special supplement — pediatric vaccination

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Purpose: At the request of providers, this special supplement to the NMCP COVID-19 Literature Report focuses on the recent approval of a COVID-19 vaccine for children aged 5–11 years old.

While every COVID report includes a section of news, journal articles, and other items of interest about pediatric population, this supplement is meant to address the specific information needs of clinicians and families regarding COVID-19 vaccination. It covers vaccination guidelines, what is and is not known about adverse effects with the vaccine, and other related issues of COVID-19 disease in children.

Some content has already been documented in previous NMCP COVID-19 Literature Reports; it is copied here for convenience. All reports are available online at
<https://nmcp.libguides.com/covidreport>.

Disclaimer: I am not a medical professional. This document is current as of the date noted above. While I make every effort to find and summarize available data, I cannot cover everything in the literature on COVID-19. Please feel free to reach out with questions, suggestions for future topics, or any other feedback.

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The Big Picture: Pediatrics

News in Brief

As of 17 November 2021, 214 children aged 0–4 years and 498 children 5–18 years old have died from COVID-19 ([CDC](#)).

More than 100,000 children a week have tested positive for COVID-19 for the past 13 weeks, with over 6.6 million children testing positive since the start of the pandemic ([AAP](#)).

"By the end of [Wednesday, 17 November 2021], 2.6 million American children ages 5 to 11 will have gotten their first shot of the Pfizer-BioNTech COVID-19 vaccine, meaning 10% of that age-group will have started the two-dose series in the first 10 days the vaccines have been available" ([CIDRAP](#)).

"Long-term study of children with COVID-19 begins — NIH-supported research will track effects of COVID-19 infection on children over three years" ([NIH](#)).

COVID-19 Vaccines in Children and Adolescents

The CDC has numerous websites that address COVID-19 vaccine recommendations for children:

- [COVID-19 Vaccination for Children 5 through 11 Years Old](#)
- [How to Talk with Parents and Caregivers about COVID-19 Vaccination — Tips for Pediatricians, Family Medicine Practitioners, Nurses, Pharmacists, Public Health Officials, & Other Vaccine Providers](#)

News in Brief

"Parents, we're here to help! Answers to your COVID vaccine questions ([NPR](#); includes audio option).

"Parents still have a Thanksgiving problem — A first COVID shot will give kids some protection, but none of them will be fully vaccinated until the beginning of December" ([Atlantic](#)).

"FDA delays decision on Moderna coronavirus vaccine for adolescents to evaluate myocarditis risk, company says. The agency says the review will take until at least January, according to the company" ([WP](#)).

"Ollie the dog helps U.S. kids with vaccine hesitancy one jab at a time" ([Reuters](#)).

Special Reports and Other Resources

FDA: [Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Document \[pdf\]](#) (26 October 2021)

This document includes the data from Pfizer presented to the FDA's VRBPAC to support approval for its mRNA COVID-19 vaccine (Comirnaty) in children aged 5–11 years old.

Journal Articles

Guidelines and Recommendations

MMWR: [The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021](#) (early release 05 November 2021)

"What is already known about this topic? On October 29, 2021, the Food and Drug Administration granted Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years.

What is added by this report? On November 2, 2021, after a systematic review of available data, the Advisory Committee on Immunization Practices made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years in the United States for prevention of COVID-19.

What are the implications for public health practice? The Pfizer-BioNTech COVID-19 vaccine has high efficacy (>90%) against COVID-19 in children aged 5–11 years, and benefits outweigh risks for vaccination. Vaccination is important to protect children against COVID-19 and reduce community transmission of SARS-CoV-2."

JAMA: [What Parents, Practitioners, and Policy Makers Need to Know](#) (05 November 2021)

"This Viewpoint discusses the Food and Drug Administration granting Emergency Use Authorization of the mRNA COVID-19 vaccine BNT162b2 for children aged 5 to 11 years and the role that will play in keeping children, schools, and communities safe."

Effectiveness

NEJM: [Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age](#) (09 November 2021)

"Background: Safe, effective vaccines against coronavirus disease 2019 (Covid-19) are urgently needed in children younger than 12 years of age.

Methods: A phase 1, dose-finding study and an ongoing phase 2-3 randomized trial are being conducted to investigate the safety, immunogenicity, and efficacy of two doses of the BNT162b2 vaccine administered 21 days apart in children 6 months to 11 years of age. We present results for 5-to-11-year-old children. In the phase 2-3 trial, participants were randomly assigned in a 2:1 ratio to receive two doses of either the BNT162b2 vaccine at the dose level identified during the open-label phase 1 study or placebo. Immune responses 1 month after the second dose of BNT162b2 were immunologically bridged to those in 16-to-25-year-olds from the pivotal trial of two 30- μ g doses of BNT162b2. Vaccine efficacy against Covid-19 at 7 days or more after the second dose was assessed.

Results: During the phase 1 study, a total of 48 children 5 to 11 years of age received 10 μ g, 20 μ g, or 30 μ g of the BNT162b2 vaccine (16 children at each dose level). On the basis of reactogenicity and immunogenicity, a dose level of 10 μ g was selected for further study. In the phase 2-3 trial, a total of 2268 children were randomly assigned to receive the BNT162b2 vaccine (1517 children) or placebo (751 children). At data cutoff, the median follow-up was 2.3 months. In the 5-to-11-year-olds, as in other age groups, the BNT162b2 vaccine had a favorable safety profile. No vaccine-related serious adverse events were noted. One month after the second dose, the geometric mean ratio of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing titers in 5-to-11-year-olds to those in 16-to-25-year-olds was 1.04 (95% confidence interval [CI], 0.93 to 1.18), a ratio meeting the prespecified immunogenicity success criterion (lower bound of two-sided 95% CI, >0.67; geometric mean ratio point estimate, ≥ 0.8). Covid-19 with onset 7 days or more after the second dose was reported in three recipients of the BNT162b2 vaccine and in 16 placebo recipients (vaccine efficacy, 90.7%; 95% CI, 67.7 to 98.3).

Conclusions: A Covid-19 vaccination regimen consisting of two 10- μ g doses of BNT162b2 administered 21 days apart was found to be safe, immunogenic, and efficacious in children 5 to 11 years of age."

See also:

- [Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents \(NEJM, 11 August 2021\)](#)
- [Letter to the editor: Effectiveness of BNT162b2 Vaccine against Delta Variant in Adolescents \(NEJM, 20 October 2021\)](#)
- [Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents \(NEJM, 15 July 2021\)](#)

Adverse Events/Side Effects

At the time of this writing, there is very little, if any, data on adverse events/side effects of the vaccine in children and adolescents, outside of the FDA approval documentation.

Treatments, Management, and Impact on Other Diseases

Journal Articles

MMWR: [Incidence of SARS-CoV-2 Infection, Emergency Department Visits, and Hospitalizations Because of COVID-19 Among Persons Aged ≥12 Years, by COVID-19 Vaccination Status — Oregon and Washington, July 4–September 25, 2021](#) (19 November 2021)

"What is already known about this topic? Studies have demonstrated that SARS-CoV-2 infection, need for emergency department (ED) visits, and hospitalization were uncommon in fully vaccinated persons before the widespread circulation of the SARS-CoV-2 B.1.617.2 (Delta) variant.

What is added by this report? Among persons aged ≥12 years enrolled in a Pacific Northwest health plan, unvaccinated persons with SARS-CoV-2 infection were approximately twice as likely to receive ED care or to be hospitalized than were vaccinated persons with COVID-19.

What are the implications for public health practice? The findings in this report support CDC's current recommendation that all persons aged ≥5 years should receive full COVID-19 vaccination, including additional and booster doses, to prevent illness and reduce transmission of SARS-CoV-2."

COVID-19 VACCINATION PREVENTS INFECTION AND SEVERE ILLNESS

*Study of patients ages 12 and up in a large health system**

Infection
3x more likely among unvaccinated compared with fully vaccinated people[†]

Hospitalization
2x more likely among unvaccinated compared with fully vaccinated COVID-19 patients

Death
7x more likely among unvaccinated compared with fully vaccinated COVID-19 patients

Vaccinate all eligible people as soon as possible

* Kaiser Permanente Northwest health plan, Oregon and Washington, July 4–September 25, 2021
† >14 days after completing authorized COVID-19 vaccination series

bit.ly/mm7046a4

CDC **MMWR**

J Clin Med: [COVID-19 in Children with Down Syndrome: Data from the Trisomy 21 Research Society Survey](#) (31 October 2021)

"Adults with Down Syndrome (DS) are at higher risk for severe outcomes of coronavirus disease 2019 (COVID-19) than the general population, but evidence is required to understand the risks for children with DS, which is necessary to inform COVID-19 shielding advice and vaccination priorities. We aimed to determine the epidemiological and clinical characteristics of COVID-19 in children with DS. Using data from an international survey obtained from a range of countries and control data from the United States, we compared the prevalence of symptoms and medical complications and risk factors for severe outcomes between DS and non-DS paediatric populations with COVID-19. Hospitalised COVID-19 patients <18 years with DS had a higher incidence of respiratory symptoms, fever, and several medical complications from COVID-19 than control patients without DS <18 years. Older age, obesity, and epilepsy were significant risk factors for hospitalisation among paediatric COVID-19 patients with DS, and age and thyroid disorder were significant risk factors for acute respiratory distress syndrome. Mortality rates were low in all paediatric COVID-19 patients (with and without DS), contrasting with previous findings in adults with DS (who exhibit higher mortality than those without DS). Children with DS are at increased risk for more severe presentations of COVID-19. Efforts should be made to ensure the comprehensive and early detection of COVID-19 in this population and to identify children with DS who present comorbidities that pose a risk for a severe course of COVID-19. Our results emphasize the importance of vaccinating children with DS as soon as they become eligible."

Front Pediatr: [Educational Setting and SARS-CoV-2 Transmission Among Children With Multisystem Inflammatory Syndrome: A French National Surveillance System](#) (26 October 2021)

"Background: Multisystem inflammatory syndrome in children (MIS-C) is the most severe form associated with SARS-CoV-2 infection in children. To reduce the spread of SARS-CoV-2 at the population level, educational setting closure have been implemented in many countries. However, the direct benefit of school closure on the MIS-C burden remains to be explored. We aimed to assess the role of educational settings in SARS-CoV-2 transmission among children with MIS-C.

Methods: We conducted a French national prospective surveillance of MIS-C, coordinated by Public Health France, from April 2020 to March 2021. During this period, we included all children with MIS-C fulfilling the WHO definition who were reported to Public Health France. For each child, we traced the source of SARS-CoV-2 transmission. The main outcome was the proportion of children with MIS-C, with educational setting-related SARS-CoV-2 infection, during the period of school opening.

Results: We included 142 children fulfilling WHO criteria for MIS-C: 104 (70%) cases occurred during school opening periods. In total, 62/104 children (60%, 95%CI [50; 69]) had been contaminated by a household contact and 5/104 in educational settings (5%, 95%CI [2; 11]). Among children with MIS-C occurring during school closure periods, the proportion of household transmission remained similar (66%, 25/38).

Conclusion: Children with MIS-C were mainly infected by SARS-CoV-2 within their family environment, and the educational setting played a marginal role in this transmission. This suggests that mitigating school attendance may not reduce substantially the burden of MIS-C."

MMWR: [Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021](#)
(10 September 2021)



"What is already known about this topic? Severe illness from COVID-19 can and does occur in children and adolescents.

What is added by this report? COVID-19 cases, emergency department visits, and hospital admissions increased from June to August 2021 among persons aged 0-17 years. Emergency department visits and hospital admissions in a 2-week period in August 2021 were higher in states with lower population vaccination coverage and lower in states with higher vaccination coverage.

What are the implications for public health? Community vaccination, in coordination with testing strategies and other prevention measures, is critical to protecting pediatric populations from SARS-CoV-2 infection and severe COVID-19."

See also: [erratum published 24 September 2021](#)

Mental Health, Psychosocial Issues, and Wellness

Special Reports and Other Resources

Virginia Department of Education: [COVID-19: A Parent Guide For School-Aged Children](#)

National Association of School Psychologists: [Helping Children Cope With Changes Resulting From COVID-19](#)

Health Messaging and Countering Misinformation

Webinars and Online Modules

The American Academy of Pediatrics (AAP) has a collection of webinars for pediatricians on caring for young patients during the pandemic. Topics include: caring for children with complex medical needs during COVID-19; family mental health and resilience; racial health inequities; and global health issues. For more details and links to the webinars, see:

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-webinars-for-pediatricians/>

WHAT: [Effective COVID-19 Vaccine Conversations](#) (AAP)

WHEN: On demand; free (with registration) online course.
Available 08 OCT 2021 – 31 DEC 2021

FOR: Targeted audiences include general pediatricians, pediatric residents and/or fellow, pediatric nurse practitioners, and physician assistants.

DETAILS: "The coronavirus disease 2019 (COVID-19) pandemic has caused tremendous burden to the U.S. population, including children and adolescents. Vaccines are safe and effective in protecting individuals and populations against infectious diseases, including COVID-19, and vaccines are currently available to provide

protection against COVID-19. This course aims to improve knowledge and competency among pediatricians and non-physicians to have effective COVID-19 vaccine conversations with patients and families, including the sharing of credible COVID-19 vaccination information and responding to misinformation."

REGISTER: <https://shop.aap.org/effective-covid-19-vaccine-conversations>

Patient Education

There are numerous sources of articles on COVID-19 written for patients and families to answer questions about COVID-19, including on getting vaccinated. Highlighted content:

CDC: COVID-19

- [COVID-19 Vaccines for Children and Teens](#)
- [Key Things to Know About COVID-19 Vaccines](#)
- [Myths and Facts about COVID-19 Vaccines](#)

American Academy of Pediatrics / [HealthyChildren.org: COVID-19](#)

- [COVID-19 Vaccine Checklist for Kids Age 5 and Up](#)
- [The Science Behind COVID-19 Vaccines: Parent FAQs](#)
- [COVID-19: What Families Need to Know](#)
- [COVID-19 and Multi-System Inflammatory Syndrome in Children \(MIS-C\)](#)
- [Post-COVID Conditions in Children and Teens](#)
- [COVID-19 and kids: How mRNA vaccines work \(YouTube video\)](#)

Ask the pediatrician:

- [Does the COVID-19 vaccine protect kids from variants of the virus like delta and delta plus?](#)
- [What side effects might my child have after a COVID-19 vaccine?](#)
- [If my child had COVID already, do they need the vaccine?](#)
- [My child is about to turn 12. Which COVID-19 vaccine should they get?](#)

Cincinnati Children's: COVID-19 Information

- [Vaccines: What You Need to Know](#)
- [Vaccine Myths and Truths](#)
- [This Is the Truth: Fertility Unaffected by COVID Vaccines](#)
- [Condition Specific Guidelines](#) (includes comorbidities and preexisting diseases/conditions such as asthma, cancer, diabetes, and patients with intellectual and physical disabilities)

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WP: Washington Post. Laurie McGinley. FDA delays decision on Moderna coronavirus vaccine for adolescents to evaluate myocarditis risk, company says. The agency says the review will take until at least January, according to the company (31 October 2021). Link: <https://www.washingtonpost.com/health/2021/10/31/moderna-vaccine-adolescents-children-delayed/>